Case 3:17-cv-01362 Document 1508-3 Filed 01/12/22 Page 1 of 5 PageID #: 71541 McKesson Corporation Paul C. Julian

Group President

McKesson Corporation One Post Street San Francisco, CA 94104 415.983 7687 Tel 415.983.9780 Fax

MSKESSON

Empowering Healthcare

January 18, 2006

By Facsimile/Confirm by Federal Express

Joseph T. Rannazzisi, Deputy Chief United States Department of Justice Drug Enforcement Administration Office of Enforcement Operations 700 Army Navy Drive Arlington, VA 22202

Dear Mr. Rannazzisi:

This letter is in response to recent meetings between McKesson Corporation ("McKesson") and the Drug Enforcement Administration ("DEA") over concerns about distribution of certain controlled substances from our Lakeland, Florida Distribution Center. For the reasons below, I was surprised and very troubled to learn that DEA was considering issuing a show cause against that facility. I am writing in the hope that these issues can be resolved without the need for formal administrative proceedings.

First, and most importantly, let me assure you and DEA that McKesson is committed to a compliance program that ensures the safe distribution of health care products, especially controlled substances. McKesson operates distribution centers nationwide that are registered with DEA to distribute controlled substances. McKesson has a long track record of leading the industry in compliance with DEA regulations. DEA compliance is part of the performance standards for our associates, well documented in our standard operating procedures (SOPs) and internally audited annually. We fully recognize our responsibility to ensure that controlled substances are secure in the supply chain.

In addition, over the last 25 years, McKesson has supported DEA in its effort to improve policies and procedures to reduce the potential for misuse and diversion of controlled substances both directly and through McKesson's membership in the Healthcare Distribution Management Association (HDMA). For example, McKesson has devoted significant resources to voluntarily assisting DEA in development of an automated order form system for narcotic drugs.

CONFIDENTIAL-SUBJECT TO PROTECTIVE ORDER

MCKMDL00571361

DEF-WV-01557.00001



Mr. Joseph T. Rannazzisi January 18, 2006 Page 2

In this regard, I must rebut any impression that McKesson has not seriously considered and responded to the information provided by DEA about the problem of "internet pharmacies." After the September meeting with DEA, senior management responsible for all McKesson distribution centers were provided with a summary of the issues raised by DEA about internet pharmacies and DEA's view of what constitutes an illegal internet pharmacy. Additionally, discussions on the appropriate next steps were reviewed and included running regional sales reports based on the criteria provided by DEA. At the September meeting, DEA identified several Colorado pharmacies by name. Upon notification that DEA had suspended the registrations of these pharmacies, McKesson immediately terminated the authority for these Colorado pharmacies to order controlled substances from McKesson.

McKesson has also distributed educational information on internet pharmacies to Operations and Sales personnel. The materials included DEA's expectations, a checklist questionnaire, and data received during the September 1st meeting at DEA Headquarters. Using the DEA questionnaire, sales personnel for all of the McKesson distribution centers reviewed their customers to determine if those customers were operating over the internet. McKesson is in the process of revising its procedures to quantify customer sales of controlled substances identified as lifestyle drugs through a central review process. This is being conducted in addition to the already established suspicious orders reporting. We are also developing alternative reporting mechanisms to enhance or replace the current suspicious order reporting system in light of information provided by DEA.

On November 21, 2005, DEA notified McKesson through outside counsel that DEA was extremely concerned about excessive distribution of hydrocodone products to six specific pharmacies in the Tampa, Florida area. McKesson immediately imposed a limitation on all of these pharmacies and cut sales of hydrocodone to these pharmacies to only 10 percent of their prior orders. McKesson also began an investigation of all of these pharmacies which included requesting additional information from the pharmacies about their customers and steps taken to verify that prescriptions filled are legitimate. McKesson sales managers have been visiting the accounts inquiring to the nature of their business activity.

I also want to clarify some confusion about DEA's notification to McKesson regarding its concern about one of the six pharmacies noted above, United Prescription

¹You had raised a particular concern about why McKesson would complete an order from United Prescription Services for 99,000 dose units placed on October 21, 2005. In checking our records, we would note that this order was in response to our advising all of our Florida customers to stock up prior to Hurricane Wilma in the event of a prolonged shut-down of the facility. The pharmacy followed that instruction and the following week reduced their order significantly.

Mr. Joseph T. Rannazzisi January 18, 2006 Page 3

Services, located in Tampa, Florida. I am providing this explanation because it is important that DEA not believe that McKesson was purposefully ignoring warnings provided by the agency. At the January 6, 2006 meeting with McKesson, DEA stated that the agency had warned McKesson about excessive sales of hydrocodone to United Prescriptions Services on two occasions: first, the September 1, 2005 meeting and second, a contact by a local DEA investigator to the Lakeland facility in October 2005. After consulting notes from the September 1, 2005 meeting, none of the representatives for McKesson at that meeting recall any discussion about this pharmacy. Two Colorado pharmacies were identified and McKesson took quick action against these pharmacies.

Also, according to government contact sheets that are required to be completed by all McKesson personnel, DEA Diversion Investigator Debra Butcher did discuss an issue with the Lakeland facility on October 5, 2005, but this did not include a discussion about United Prescription Services, but rather another pharmacy, Lexus Drugs. McKesson had several discussions with Ms. Butcher about this pharmacy in early October because it was a new account and there was some concern about the pharmacy's dispensing practices. Ms. Butcher ultimately informed McKesson that she did not see an issue with opening this account because they had "discontinued doing what they were doing." However, McKesson ultimately decided to be cautious and did not open an account with Lexus Drugs.

McKesson has been contacted by legal counsel representing some of the affected pharmacies, claiming that the pharmacies are conducting business legally and McKesson is harming their business by arbitrarily limiting their access to product. These pharmacies have claimed to be filling legitimate prescriptions and to be taking appropriate steps to verify that the prescriptions are being written pursuant to a legitimate doctor-patient relationship. These companies have provided information on the procedures used to verify practitioner licenses and examination of patients.

Nevertheless, in light of DEA's strong assertion at the January 6, 2006 meeting that these pharmacies are "internet pharmacies" McKesson as of January 9, 2006, has terminated sales of controlled substances to all six pharmacies.

The internet provides unique challenges for distributors and increasingly requires them to devise policies and procedures that go beyond traditional methods of verifying customer's pharmacy dispensing practices. McKesson serves tens of thousands of customers nationwide and sales of controlled substances and other drugs to these customers varies greatly based on the size of pharmacy and other characteristics of the pharmacy's specific practice. For example, the Lakeland DC serves about 1700 customers and more than 1400 purchase controlled substances from the facility. DEA has stated that monthly sales of over 5,000 dosage units of hydrocodone should be used

Mr. Joseph T. Rannazzisi January 18, 2006 Page 4

as a flag as to whether the pharmacy is dispensing legitimate prescriptions. However, excluding the six pharmacies identified by DEA, more than 85 other pharmacy customers order more than 5,000 dosage forms of hydrocodone per month from this facility. This is to illustrate that the task of identifying suspicious sales will require that McKesson develop better systems and closer collaboration with DEA. We are prepared to do both.

In summary, please accept my assurance that McKesson will continue to be a good corporate citizen and cooperate with DEA and other agencies to reduce the potential for misuse for diversion of drug products. We welcome the opportunity to work with DEA to help identify and close down illegal internet pharmacies. To this end, I hope that DEA and McKesson can resolve these issues without the need for formal administrative proceedings. Especially given McKesson's commitment to support the mission of DEA and its history of DEA compliance at all of its distribution centers, I am confident this is possible.

I would like to discuss a possible resolution to this matter with you as soon as possible. I will contact your office to schedule a time that would be convenient.

Sincerely,

Paul C. Julian

Executive Vice President, Group President

McKesson Corporation

cc: Michael Mapes, Office of Diversion Control Charlie Trant, Office of Chief Counsel John A. Gilbert, Esq., Hyman, Phelps & McNamara

Mr. Joseph T. Rannazzisi January 18, 2006 Page 5

bcc: Pat Blake

Jack Hannon
Gary Hilliard
Iver Kern
Bill Mahoney
Steve Miller
Ina Trugman
Don Walker